



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,077	06/23/2004	Stephen Proulx	MCA-589A PC/US	5860
25182 7590 04/14/2009 MILLIPORE CORPORATION 290 CONCORD ROAD BILLERICA, MA 01821				
EXAMINER				
BOUCHELLE, LAURA A				
ART UNIT		PAPER NUMBER		
3763				
MAIL DATE		DELIVERY MODE		
04/14/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/500,077

Applicant(s)

PROULX ET AL.

Examiner

LAURA A. BOUCHELLE

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 5, 11, 14-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 102

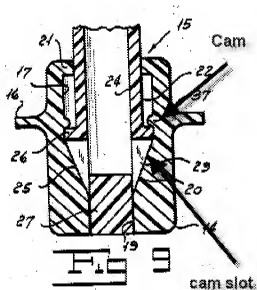
1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 2, 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Mackal (US 2859932). Mackal discloses a valve having a body 14 having a bore through its interior, a movable plunger 27 contained in the bore, the plunger having a port 29, in the closed position the plunger is in alignment with the face of the body forming a steamable surface, the plunger has a cam 26 and the body has a cam slot which receives the cam (as can be seen in Fig. 9). The plunger has a handle 22 to move the plunger within the bore. The bore has three sections each with a different diameter, the second diameter is greater than the first diameter and a tapered portion is located there between. The plunger has a diameter less than that of the bore and one or more openings 29 forming a fluid channel with the second end of the plunger. The plunger is received within the bore and therefore, the diameter must be smaller, even if there is frictional engagement between the two components because if they had identical diameters the plunger would not fit within the bore. Furthermore due to the contours of the plunger and the bore, there are portions of the plunger that have a diameter that is much smaller than the diameter of portions of the bore. The overall shape of the plunger corresponds to the shape of the bore as can be seen in Figs. 6-9.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 4, 5, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mackal in view of Tessman et al (US 6210372). Claims 4, 5, 11 differ from Mackal in calling for the device to be formed of polyetherimides. Tessman discloses a storage and delivery device for a catheter or needle wherein the device is made using thermoplastics such as polyetherimide that have high hardness and strength and can withstand sterilization (Col. 6, lines 55-60). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to form the device of Mackal of a thermoplastic such as polyetherimide so that the device would be able to withstand sterilization.
5. Claims 14, 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mackal in view of Leason et al (US 5360413). Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mackal in view of Tessman as applied to claim 11 above, and further in view of Leason et al (US 5360413). Claims 14, 15, 21, 22 differ from the teachings above in calling for the first face to include a sanitary flange. Leason teaches an access device having elements similar to that of Mackal but further including a sanitary flange 25 that allows the device to be attached to a component without contamination. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Mackal to include a sanitary flange as taught by Leason to prevent contamination when the access device it attached to a component.

Response to Arguments

6. Applicant's arguments filed 12/18/08 have been fully considered but they are not persuasive. Applicant argues that the device of Mackal does not disclose a material that is steam sterilizable. The claim requires that the device forms a steamable surface and a sterile barrier. The device of Mackal forms a steamable surface because any surface is steamable. Since the plunger forms an air tight fluid tight seal it is a sterile barrier between the materials contained within the bore and the outside environment.
7. Applicant argues that Mackal discloses a plunger that has an outer diameter at several if not all locations that is equal or greater to that of the bore. The examiner argues that the plunger also has a diameter that is smaller than that of the bore in several locations. The plunger meets the claim limitations because it has a diameter at least in part that is smaller than that of the bore.
8. Applicant argues that Mackal fails to teach a cam and a slot. Figure 9 of Mackal is annotated below. The cam slot is formed between the projection 37 and the distal end of the body, and the cam extends therein.



9. Applicant argues that Mackal fails to disclose a handle on the plunger. Applicant has not disclosed the structure of the handle so it is interpreted that a handle is any portion that may be grasped such as the portion 22 of the plunger that is extending out of the body.
10. Applicant argues that one of skill in the art would not substitute the material of Mackal for the more rigid material of Tessman. Mackal discloses that *preferably* the device is formed from a material that may be distorted. One of skill in the art would know that there are many different ways to assembly a valve.
11. Applicant fails to claim the structure of the sterile flange. The examiner believes that any flange may be a sterile flange if it has been sterilized. A sterile flange is interpreted to be the same as a flange for the purposes of examination absent any other identifying structures.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle
Examiner
Art Unit 3763

/Laura A Bouchelle/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763